UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
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SEP 16 2003

David J. Levy PhD
Patent Counsel
Glaxo Wellcome Inc.
Five Moore Drive, PO Box 13398
Research Triangle Park NC 27709-3398

Re: Patent Term Extension
Application for
U.S. Patent No. 5,360,800

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,360,800, which claims the human drug product LOTRONEX® (alosetron hydrochloride), and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,076 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,076 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of November 14, 2002 (67 Fed. Reg. 69015). Under 35 U.S.C. § 156(c):

Period of Extension = 1/2 (Testing Phase) + Approval Phase
= 1/2 (3,339 - 1,637) + 225
= 1,076 days

Since the regulatory review period began May 10, 1990, before the patent issued (November 1, 1994), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 10, 1990 to and including November 1, 1994 is 1,637 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(c)(3), nor 35 U.S.C. § 156 (g)(6) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,360,800
Granted:	November 1, 1994
Original Expiration Date[1]:	February 2, 2010

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Applicant:	Ian H. Coates, et al.
Owner of Record:	Glaxo Group Limited
Title:	TETRAHYDRO-1H-PYRIDO [4,3-b]INDOL-1-ONE DERIVATIVES
Classification:	514/215
Product Trade Name:	LOTRONEX® (alsoetron hydrochloride)
Term Extended:	1,076 days
Expiration Date of Extension:	January 13, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: LOTRONEX® (alsoetron hydrochloride)
FDA Docket No.: 01E-0420